4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0280]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0396. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Financial Disclosure by Clinical Investigators

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

In the *Federal Register* of December 2, 2021 (86 FR 68500), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

Table 1 shows information that is the basis of the estimated number of respondents in tables 2 through 4.

Table 1.--Estimated Number of Applications, Clinical Trials, and Investigators Subject to the Regulation by Type of Application[1]

Application Type	Total No. of Applications	No. of Applications Affected	No. of Trials	No. of Investigators
Drugs:				
New drug application (NDA), new molecular entity (NME)	55	55	3 to 10	3 to 100
NDA non-NME	78	37	3 to 10	3 to 100
NDA efficacy supplement	196	119	1 to 3	10 to 30
Abbreviated new drug application (ANDA)	821	1	1.1	2
ANDA supplement	10,894	1	1	2
CBER Biologics:				
Biologics license application (BLA)	10	10	3 to 10	3 to 100
BLA efficacy supplement	30	30	1 to 3	10 to 30
CDER Biologics:				
BLAs	25	25	3 to 10	3 to 100
BLA efficacy supplements	102	65	1 to 3	10 to 30
Medical Devices:				
Premarket approval (PMA)	39	39	1 to 31	10 to 20
PMA supplement	29	29	1 to 3	3 to 10
Reclassification devices	0	0	0	0
510(k)	3,947	247	1	3 to 10
De Novo requests	63	57	1 to 3	10 to 20

[1] Source: Agency estimates.

FDA estimates the burden of this collection of information as follows:

Reporting Burden

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

FDA estimates that almost all applicants submit a certification statement under § 54.4(a)(1) and (2). Preparation of the statement using Form FDA 3454 should require no more than 1 hour per study. The number of respondents is based on the estimated number of affected applications.

When certification is not possible and disclosure is made using Form FDA 3455, the applicant must describe, under § 54.4(a)(3), the financial arrangements or interests and the steps that were taken to minimize the potential for bias in the affected study. As the applicant would be fully aware of those arrangements and the steps taken to address them, describing them will be straightforward. The Agency estimates that it will take about 5 hours to prepare this narrative. Based on our experience with this collection, FDA estimates that approximately 10 percent of the respondents with affected applications will submit disclosure statements.

Table 2.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Certification--54.4(a)(1) and (2)--Form FDA 3454	715	1	715	1	715
Disclosure--54.4(a)(3)--Form FDA 3455	72	1	72	5	360
Total					1,075

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping Burden

Under § 54.6 (21 CFR 54.6), the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for 2 years after the date of approval of the applications. Sponsors of covered

studies maintain many records regarding clinical investigators, including protocol agreements and investigator résumés or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

Table 3.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[2]
Recordkeeping--54.6	715	1	715	0.25	179

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Third-Party Disclosure Burden

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family, and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that the time required for this task may range from 5 to 15 minutes; we used the median, 10 minutes, for the average burden per disclosure (see table 1).

Table 4.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
54.4(b)--Clinical Investigators	13,082	1	13,082	0.17	2,224

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

The burden for this information collection request has changed since the last OMB approval. Our estimated burden for the information collection reflects a 298 hour increase. We have adjusted our estimated burden for the information collection to reflect the number of submissions we received in the last few years. Additionally, for products regulated by the Center for Devices and Radiological Health, we now include De Novo requests as a type of application that may rely on clinical studies. Upon review, we have corrected an inadvertent omission regarding the number of BLAs and BLA efficacy supplements received by our Center for Drug

Evaluation and Research and used, in part, as a basis for calculating the cumulative burden estimate. We have corrected that error here, as reflected in table 1.

Dated: March 24, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs,

U.S. Food and Drug Administration.

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